MAY 11 2001

K003504

510(k) Summary of Safety and Effectiveness
[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:	PLUS ORTHOPEDICS 6055 Lusk Blvd. San Diego, CA 92121 Tel: 858-550-3800 x 2506 Attn: Mr. Hartmut Loch, RAC Director, Regulatory Affairs
Trade name:	RT-PLUS™ Knee System
Common name:	Hinged Knee Prosthesis
Classification name:	Prosthesis Knee, Femorotibial, Constrained, Cemented, Metal/Polymer § 888.3510 - Class II - Product Code: KRO - 87 Orthopedic Device Panel
Predicate Device:	Encore Hinged Knee, K982160 (S/E 3/17/99), also known as the RT-PLUS™ Knee is manufactured by PLUS Endoprothetik AG, Switzerland
Device Modification Description:	The RT-PLUS™ Knee System is a rotating hinged knee prosthesis that is identical to the predicate device. In addition we have added a variety of modular stems. This gives the surgeon the flexibility to adapt longer stems for either the femoral or the tibial component during surgery. The modular components can be used with either the femoral or tibial components. The tibial PE inserts have not been changed and are identical to the predicate device.
Indications:	The RT-PLUS™ Knee System is a tri-compartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use as a replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The RT-PLUS™ Modular Cemented Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Biomechanical tests have been performed. The test results of the additional modular cemented components were equivalent to the predicate device and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2001

Mr. Harmut Loch, RAC
Director of Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, CA 92121

Re: K003504
Trade Name: RT PLUS™ Knee System
Regulation Number: 21 CFR §888.3510
Regulatory Class: II
Product Code: KRO
Dated: February 9, 2001
Received: February 12, 2001

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K003504

Device Name(s):

RT-PLUS™ Knee System

Indications for Use:

The RT-PLUS™ Knee System is a tri-compartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use as a replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The RT-PLUS™ Modular Cemented Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)